PSJ3

Exhibit 436

Prescription Drug Regulation Policy to Minimize Misuse and Abuse

Background

Over the course of the last decade, prescription drug abuse controlled substances, and diversion of same in the course of legitimate pharmacy practice, have become serious public policy problems in the United States. On one hand, large numbers of persons, treatment dollars, and related economic and non-economic costs have been associated with the misuse of prescription drugs (the latter notably including important opioid analgesics such as Oxycodone and Methadone, as well as therapeutic stimulants such as Methylphenidate and Dextroamphetamine).   On the other hand, the same drugs also have important and legitimate medical applications. Efforts to restrict access and supply have the potential to exacerbate a vulnerable supply chain, and to make the medications unavailable to persons who legitimately need them. Policymakers and enforcement authorities have struggled to find an optimal balance, in combatting the diversion of medications to illicit users, while simultaneously protecting the legitimate distribution channel to ensure access to medication through valid prescriptions.

Recent DEA efforts to stem drug diversion, and the impact of those efforts on distributors and retail pharmacies, raise a series of basic questions for policymakers. How large is the problem of drug diversion in the United States, and how has this problem developed and changed over time? What are the broader social and policy challenges posed by diversion and abuse of prescription drugs, spanning a range of medical, public health, law enforcement, consumer, and pharmaceutical perspectives?   What has the impact been of the DEA focus on distributors, either in terms of reducing drug diversion, or in terms of the costs and supply-chain effects imposed on the industry? What are the origins of the DEA's "chokepoint" policy, and what are some of the alternative policies that could plausibly be pursued to combat the diversion of drugs?   Are there any state policies that have been particularly effective at assisting with targeting diversion while imposing fewer costs on patients and the industry? Finally, is there any rigorous basis for assessing the costs and benefits of the current DEA approach, as compared with specific policy alternatives or avenues for reform?

Proposal

We propose to undertake a study that would address several of these basic questions.   Our approach will involve delineating a series of tasks, each one specifically addressing a policy question to be explored. At present, we believe that there are five key questions that we would need to address for a comprehensive study. First, what does recent trend data on Schedule II, III & IV drug abuse and diversion (including street prices) actually show, and how should we interpret relevant descriptive data in light of recent history and government policies? Second, what are some of the key medical, public health, and consumer implications of Schedule II, III, and IV drug abuse and diversion, and in turn, how do those impact on the criminal and law enforcement dimensions of the diversion problem? Third, what are the regulatory and legislative history origins of the DEA's recent "chokepoint" strategy with regard to distributors, and what data are available to

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show the various effects of DEA enforcement under that policy? Fourth, what is the range of plausible policy alternatives that might be pursued, either to engage distributors and pharmacies more directly as law enforcement allies and collaborators in the fight against drug diversion, or else to attack drug diversion through a different set of leverage points? Finally, what kinds of empirical assessment and insight can we offer regarding the costs and benefits of the different policy approaches, drawing either from historical quantitative data, case study analogies, simulations, etc.?

Each of these tasks can be undertaken as a largely discrete research activity. Across the tasks, we anticipate drawing on a mix of qualitative and quantitative empirical methods, review of relevant regulatory and scholarly materials, construction of illustrative case studies, elite interviewing and focus group activities, and engagement with an expert advisory panel. Some of the listed tasks are notably more data intensive (e.g., recent trends in drug abuse and diversion), while others are more policy oriented (e.g., origins of the current enforcement strategy, examination of state policy options) or analytical (e.g., consideration of alternative enforcement strategies).   In our view and subject to the scope of the eventual project, we believe that a broad approach to multiple research questions touching on prescription drug abuse and diversion, drawing on a combination of methods and activities, is likely to produce a more useful and influential product than would a narrower approach.

There is a range of additional tasks that we could undertake in connection with this study. For example, one obvious thing we could do as a culminating step would be to invite key stakeholders among the pharmacy distributors, retail pharmacy chains, consumer groups and healthcare organizations, and law enforcement community to participate in a roundtable meeting or conference, either with the aim of sharing findings from our research project, or with the aim of stimulating a path-breaking dialog on relevant policy issues. Although less focal to the core research questions being asked, such a meeting could be a helpful way to draw attention to these issues, and perhaps to engage DEA and other policymakers in a constructive and non-confrontational setting. Such a meeting might also serve as a useful step for thinking about a simulated cost-benefit analysis that could consider policy options not yet being considered or adopted by states or the federal government.

Advisory Panel

Another important aspect of the project is the organizing of an expert advisory panel, both to provide primary input on a range of questions related to drug abuse and diversion, and to review and strengthen the eventual product our research. Typically, one of the aims of putting together an advisory panel like this is to provide additional independent oversight, and to make it clear that a range of stakeholders with different points of view are represented and engaged in contributing to the work. Another aim involves our being able to draw directly on the expertise of specific panel members, with regard to questions where that expertise would be directly helpful and relevant. Given these sorts of considerations, we'd ideally want to bring together a group that included distinguished representatives with backgrounds in law enforcement and executive branch service, public health, medicine, consumer advocacy, pharmacy, and business. Larry Thompson, Dick Thornburgh, and Jonathan Caulkins are all examples of potentially appropriate people to

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include on such a panel, and with whom RAND already has some working relationship. We plan to consult with you further about other potential candidates, and categories of candidates, to involve in such a panel.

Many of the details concerning exactly what a panel might look like, and what it would do, are open to discussion. Our initial thought is that a group of 8 to 12 people, convened physically at the beginning and near the end of the project, with some interim conference calls, seems like it might be about the right balance to strike.

Deliverables, Timeline, and Budget

The primary deliverable from the project would either be a RAND research report (formally published and distributed through RAND's website), and/or one or more peer-reviewed journal articles placed in major medical or policy journals. We might want to reserve flexibility regarding which of these pathways we would try to pursue, depending on the findings we generate (and whether these lend themselves to journal publication. We typically would also generate a RAND research brief (RB), which is typically a glossy, stand-alone 2 or 3 page document that summarizes major findings from the primary research publication. Additional deliverables potentially could involve a symposium meeting as described above; in-person and telephone briefings to be given by the lead researcher on the study to the sponsors and/or to others; etc.

On the assumption that we want the project to address all of the issues we've suggested here, we propose an 18-24 month effort, with the aim of producing a draft report for review by the panel after 15 months. To the extent that data analysis of legal policies and/or secondary data are deemed an important objective, additional time may be needed to gain access to the relevant data. Alternately, we could set the project up to produce several discrete products and interim deliverables (e.g., publishable article manuscripts connected with different project tasks). Particularly if we start the project with an initial stage of seed funding from HDMA and its affiliates, it seems likely that we would begin by focusing intensively on the first couple of project tasks, recruiting an advisory panel, and reaching out to additional potential funders, with the aim of completing the work on these elements in the first 9 to 12 months following project launch.

With regard to the funding model for the project, we are currently envisioning that the majority of the funding would come from HDMA and its affiliates. However, we would also like to reach out to other (non-aligned) parties with an interest in the same set of policy topics, in order to establish a broader consortium of funders to support the work, as well as to draw from them their own expert input and commentary. We think that we can make an effective marketing pitch to outside groups on the premise that we have already obtained committed private-sector funding to do a major study on drug diversion issues, but that RAND is only interested in conducting such a study if we can ensure genuine independence and objectivity. Consequently we're looking to obtain (at least) modest support and involvement from a broader group of stakeholders, both to protect our independence, and also to contribute a range of perspectives and views among the supporters to the study. We are also pursuing grant funding from the National Institutes of Health for particular pieces of the proposed project (an qualitative assessment of enforcement of state prescription drug policies), but the review cycle for funding from NIH is lengthy and uncertain.

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With this in mind, we currently envision a two-stage funding model for carrying out this project. First, an initial grant from HDMA and its affiliates would allow us to conduct preliminary research, develop a robust methodology, recruit a high-level outside advisory panel, and reach out to the most relevant stakeholders, while taking the first couple of research tasks to near completion. The second phase of funding would hopefully draw on a broader consortium of funders, including other (non-distributor) industry and professional groups, foundations (e.g. Robert Wood Johnson Foundation, Gates Foundation etc.), and possible government funders (CDC, NIDA).

Again, per earlier discussion, we are currently conceiving of this project as approximately a $1M effort, with the bulk of that funding anticipated coming from HDMA and its affiliates. Depending on how successful we are in mobilizing other outside support for the second phase of the study, potentially we might be able to raise more than $1M in total. Given that there are ample questions that could usefully be explored on drug-diversion related issues, we can certainly do a larger study if it turns out that our fund-raising outreach is particularly fruitful. In sum, we anticipate that the ultimate scope and depth of the project will depend partly on how successful we are in raising additional money, to supplement the funding provided by HDMA and its affiliates.

RAND Qualifications and Staff

RAND Law, Business, and Regulation (LBR), a research division of the RAND Corporation, is dedicated to conducting research in the areas of civil justice, corporate ethics and governance, and business regulation more generally.   LBR serves policymakers and executives both in government and in the private sector through research and analysis on controversial and challenging issues in these areas.   LBR work builds on a long tradition of RAND research characterized by an interdisciplinary, empirical approach to public policy issues, with rigorous standards of quality, objectivity, and independence. Previous LBR projects with relevance to the current proposal have focused on issues ranging from corporate governance, compliance and regulation, to aspects of pharmaceutical products liability.

The research team will also draw on expertise from RAND's Drug Policy Research Center, which is a multi-disciplinary research center already engaged in conducting work on prescription drug abuse. Rosalie Liccardo Pacula, the co-director and a Senior Economist, currently leads a project for the Department of Defense (DoD) examining prescription drug abuse in the military and is the principal investigator on several NIH grant proposals currently being reviewed related to prescription drug policy. The purpose of the DoD project is to model prescription drug abuse among military service members and assess the extent to which evidence based prevention and treatment programs, including brief interventions and drug testing, are effectively reducing use. Dr. Pacula has worked extensively with survey data on drug use in household, school-based, and military settings, has examined health care data systems identifying use, and drug market data available through the DEA's System to Retrieve Information from Drug Evidence (STRIDE) data system and the National Institute of Justice's ADAM survey.   Dr. Pacula also has extensive experience evaluating and analyzing state laws pertaining to drug policy, including the scheduling of illicit

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and prescription drugs, policies targeting prescursor chemicals for methamphetamine, and medical marijuana policies.

James Anderson, JD will serve as the overall project leader. Anderson is a Social/Behavioral Scientist with the RAND Corporation, and his previous work has included studies of the judiciary, of courts, criminal sentencing and policy and medical marijuana policy. Prior to joining RAND, he practiced criminal litigation for ten years. Dr. Rosalie Pacula will serve as the scientific lead on tasks involving data collection, analysis, and quantitative policy evaluation.   Michael Greenberg will serve the project in a senior advisory role. Additional staff will include Nancy Nicosia (Economist), Andrew Mulcahy (Policy Analyst), Srikanth Kadiyala (Economist) and Priscillia Hunt (Economist).

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